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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 08/894,548 | 08/21/1997 | YIMIN QIN | 7250-3 | 9091 |
| 7590 | 01/06/2004 | | EXAMINER | |
| THOMAS Q. HENRY WOODARD EMHARDT NAUGHTON & MCNETT 111 MONUMENT CIRCLE SUITE 3700 INDIANAPOLIS,, IN 46204 | | | LEWIS, KIM M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | 28 |
| | | | DATE MAILED: 01/06/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

S/N

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 08/894,548 | QIN ET AL. | |
| | Examiner | Art Unit | |
| | Kim M. Lewis | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 20-22,24,25,28-39,41,43,44,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 20-22,24,25,28-39,41,43,44,46 and 47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> . |

DETAILED ACTION

Response to Amendment

The amendment filed on 10/13/03 has been received and made of record in the application file wrapper. Claims 35, 43, 44 and 47 have been amended as requested.

Claims 1-19, 23, 26, 27, 40, 42 and 45 have been canceled and Claims 20-22, 24, 25, 28-39, 41, 43, 44, 46 and 47 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47, 20-22, 24, 25, 28-33, 36, 37, 41-44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,830,496 ("Freeman") in view of U.S. Patent No. 5,782,787 ("Webster") and U.S. Patent No. 5,674,524 ("Scherr").

As regards claim 47, Freeman discloses a wound dressing (Fig. 3) comprising a first wound contact layer (11) including an alginate and constructed from a non-woven material (col. 3, lines 35-38 and lines 59-63) and a second non-woven layer (12) of greater hydrophilicity since it contains a superabsorbent (col. 5, lines 4-9 and 15-18). Freeman additionally discloses a top or outer surface layer constructed from a porous stretchable material. Freeman fails to teach that the outer surface layer is a film layer and that the first and second layers are needled together.

Webster, however, teaches it is conventional in the art to place a porous stretchable film layer over an absorbent layer for the purpose of regulating water vapor loss from the wound area beneath the dressing.

It would have been an obvious design choice to one having ordinary skill in the art to substitute the porous stretchable layer of Freeman for the porous stretchable film layer of Webster since they perform the same function of regulating water vapor loss

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from the wound area. Such a substitution results in an **equivalent exchange** of one breathable, stretchable layer for another. The applicant should additionally note that an increased MVTR in the presence of liquid water as compared to moisture vapor alone is inherent.

As to the needle punching, Scherr teaches that it is conventionally known to needle punch a non-woven web of alginate fibers to another layer such that the fibers from the alginate layer penetrate into and are interlocked with another layer thereby affixing the alginate layer to another layer. This is done primarily to strengthen the alginate layer and to increase absorbency (abstract and col. 3, lines 9-24).

It would have been obvious to one having ordinary skill in the art to modify the means by which the first and second layers of Freeman are attached to include needle punching since needle punching improves absorbency and long-term stability of the dressing, as taught by Scherr.

As regards claims 20 and 21, Freeman discloses that layer (i) may be a non-woven layer and that layer (ii) is constructed from superabsorbents. As such, layer (ii) has greater hydrophilicity than layer (i).

Freeman fails to teach that layer (ii) has twice the hydrophilicity as that of layer (i) and even further fails to teach that layer (ii) has 3 to 5 times the hydrophilicity as that of layer (i). However, since Freeman provides several methods of incorporating the superabsorbent material into layer (ii) (col. 5-col. 6), the examiner contends that the manner in which the superabsorbent material is applied to layer (ii) affects the hydrophilicity of that layer. As such, depending upon the required hydrophilicity of layer

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(ii), one having ordinary skill in the art would select one method of incorporation of the superabsorbent over another as an obvious design choice.

It then follows that the hydrophilicity of each layer is an obvious design choice based upon the selected materials for each layer and the method by which the superabsorbents are incorporated into layer (ii).

As regards claims 22, 28, 29, 32 and 36, Freeman and Webster disclose the claimed invention except for the particulars of the thickness of the layers, the choice of material, and the MVTR as claimed in claims 22, 28, 29, 32 and 36. It would have been an obvious matter of design choice to add these particulars to the modified device of Freeman since the applicant has not disclosed that the particulars solve any stated problem or are for any particular purpose, and it appears that the invention would perform equally well with different thicknesses, MVTR values, and materials.

Whether these particulars solve any particular problem or produce any unexpected result, I must conclude that they are merely matters of engineering design choice, and thus do not serve to patentably distinguish the claimed invention over the prior art. *In re Kuhle*, 526 F.2d 53, 188 USPQ 7 (CCPA 1975).

Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be disclosed in the specification or supplied by affidavit. *In re Cole*, 140 USPQ 230 (CCPA) 1964).

As regards claim 24, the examiner contends that the first layer of Freeman is **capable** of debridement.

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As regards claim 25, note col. 3, lines 59-64 of Freeman, which discloses that alginate is delivered to the wound.

As regards claim 30 and 31, note col. 5, lines 36-48 of Webster, which discloses the MVTRs.

As regards claim 33, note col. 5, lines 46-48 of Freeman, which discloses the use of polyurethane.

As regards claim 37, Freeman discloses the use of calcium alginate (col. 3, line 63).

As regards claims 41 and 46, both Freeman and Webster fail to teach that the wound-contacting layer comprises felt. Absent a critical teaching and/or a showing of unexpected results derived from the use of felt in the wound contacting layer, the examiner contends that the use of felt is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 43 and 44, both Freeman and Webster fail to disclose that the wound-contacting layer comprises zinc alginate or silver alginate. However, since Freeman discloses the use of calcium alginate and sodium alginate, the examiner contends that the addition of an equivalent alginate, namely, zinc alginate or silver alginate, both of which are conventionally known for their wound healing effects, would have been *prima facie* obvious to one having ordinary skill in the art.

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Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Webster and Scherr as applied to claim 47 above, and in further view of U.S. Patent No. 5,632,731 ("Patel").

As regards claims 34 and 35, Freeman and Webster fail to teach adhesive provided on the film for bonding to the skin. However, Patel teaches it is known to provide wound dressings having film layers with a hydrocolloid (hydroactive) adhesive thereon for the purpose of bonding the dressing to the user's skin and absorbing wound exudate.

It would have been obvious to one having ordinary skill in the art to provide the modified dressing of Freeman with a hydrocolloid (hydroactive) adhesive layer for purposes of bonding to the wound dressing to the user's skin and absorbing wound exudates.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Webster and Scherr as applied to claim 47 above, and in further view of U.S. Patent No. 4,363,319 ("Altshuler").

As regards claim 38, both Freeman and Webster fail to teach the wound contact layer is comprised of a material, which promotes clotting via agglutination. However, the examiner contends that the addition of any medicament to the wound contact layer for treatment of the wound would have been *prima facie* obvious to one having ordinary skill in the art.

Additionally, the applicant should note that Altshuler teaches it is conventionally known to provide bandages with material that promotes clotting via agglutination (e.g. thrombin).

In view of Altshuler, it would have been obvious to one having ordinary skill in the art to provide the modified dressing of Freeman with blood clotting material in order to stop bleeding.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Webster and Scherr as applied to claim 47 above, and further in view of U.S. Patent No. 4,960,413 ("Sagar et al.").

As regards claim 39, both Freeman and Webster fail to teach the use of chitosan. However, Sagar et al. teach it is conventional to provide wound dressings with chitosan for its wound healing properties.

In view of Sagar et al., it would have been obvious to one having ordinary skill in the art to provide the modified dressing of Freeman with chitosan for its wound healing properties.

Response to Arguments

Applicant's argument with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

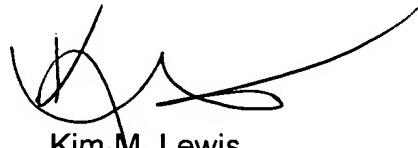
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



Kim M. Lewis
Primary Examiner
Art Unit 3761

kml
January 5, 2004